MASTERSIZER 3000 SOFTWARE: v3.81 (PSS0223-28)
SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0223-28: version 3.81 of the software for the Mastersizer 3000 laser diffraction system and the Mastersizer 3000E system. It covers software issues fixed and new features introduced. This information is required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the new features provided and resolved software issues must be weighed against the risk of new issues that may be introduced to vital areas of the software or possible changes to the results of future analysis. Installation instructions are provided.

This software release contains important security and compliance updates. As such, we strongly recommend that you upgrade to this version of the software at your earliest convenience.

Installation

It is assumed that you have authority to install or update software within your facility. It is also assumed that you have Administrator rights for the system upon which the software is installed, as this is a requirement of the installation process. If you do not have this authority, please consult with your I.T. support department before proceeding.

Recommended System Requirements

The recommended computer system requirements for running this software are highlighted in table 1 below. The software can be operated using Windows 10 (Pro and Enterprise), Windows 7 32 bit (Pro, Enterprise and Ultimate) and Windows 7 64 bit (Pro, Enterprise and Ultimate). However, it has been fully tested using Windows 10 Pro (64 bit) (v1903). Windows 10 Pro (64 bit) is therefore the preferred operating system.

Supported Languages

The Mastersizer 3000 software currently supports operation in the following languages:

- English
- French
- German
- Japanese
- Chinese (simplified)
- Russian
- Polish
- Spanish

The language used by the application is automatically configured based on the operating system settings. If you want to force the application to use English instead of the operating system language, you need to start the application using the Mastersizer 3000 (English) start menu shortcut.

Table 1: Recommended system requirements for the Mastersizer 3000 software.

Feature	Specification
Processor Type	Intel Core i7 Processor (Quad Core, 4th generation or higher)
Memory	8GB
Hard Disk Storage	250GB
Additional Storage Media	CD-ROM or DVD +/-RW drive
Display Resolution	1920 x 1080 (Minimum 1440 x 900)
Connectivity	1 USB2.0 or USB3.0 port
Operating System	Windows 7 (32 bit - Pro, Enterprise and Ultimate) Windows 7 (64 bit - Pro, Enterprise and Ultimate) Windows 10 Enterprise (64 bit - Pro and Enterprise) * * Preferred Operating System

Note:
In order to address Windows 7 vulnerabilities associated with driver signing, this software only uses the latest driver authentication protocol recommended by Microsoft (SHA 256 certification). As a result, a Windows OS update may be required in order for the system to work. Please refer to Microsoft Knowledgebase reference KB3033929 for details. Any computer system which has been updated with Microsoft patches since March 2015 should operate correctly.

Installation Instructions

The software suite comes on an auto-loading CD-ROM. Inserting the drive into a system configured to auto-run a CD will run the installation program automatically. If your system does not support this feature, run the *\Mastersizer 3000\setup.exe* program from your CD drive. If you are installing the software from a web download, then browse to the folder where the files have been extracted to and then launch the *\Mastersizer 3000\setup.exe* program.

Note:
It is important that the software is installed before the Mastersizer 3000 / 3000E instrument is connected to the computer and switched on. This will ensure that the instrument drivers are enabled, and that the firmware updates associated with this release are correctly downloaded to the instrument.

Note:
Any firmware updates required for your system will be installed at the same time as the software. It is important to keep the firmware and software 'in sync', since this is the configuration that will have been tested by Malvern Panalytical prior to release of the software.

Note:
If you are upgrading from a previous version of the software and have auditing enabled, you may see a message referring to an audit trail upgrade on the first initialization of the software.

Installing the Malvern Access Configurator (MAC) Application

The software suite includes a copy of the Malvern Access Configurator tool that allows you to manage the security aspects of the Mastersizer 3000 / 3000E. The MAC software may be installed either on the computer used to control the instrument or a separate networked computer. Installing on a separate computer allows you to manage the security centrally.

Note:
The MAC software does not auto-install. To install this software, navigate to the |*Malvern Access Configurator* folder on the software CD-ROM and run the setup.exe file.

As with all Windows applications, the MAC software must be installed by a user who is an administrator on the host computer. In addition, the MAC software uses the existing Microsoft Windows users and groups configured on the host computer to control access to the Mastersizer 3000 application. As such, prior to installing the MAC, it is important to ensure that the computer running the Malvern software is installed on its host network. If the computer is a stand-alone system, the required users and groups must be configured on the computer prior to the use of the MAC.

Given the above requirements, it is advised that a user's local IT department should review the requirements for use of the MAC application. An IT representation should also be present during the software installation process.

Note:
Please read *MAN0602-XX – Malvern Access Configurator (MAC) User Guide* and *MRK1747-xx – Mastersizer 3000 - 21 CFR Part 11 Guide* for more information as to how to use the MAC application, particularly when operation is required in a 21CFR Part 11 compliant environment. Note that operation in 21CFR Part 11 mode is not available for Mastersizer 3000E users.

Uninstall Procedure

The software can be uninstalled using the standard Add/Remove Programs feature in the *Windows Control Panel*.

Note:
Downgrading v3.81 with 21CFR11 mode enabled to earlier versions of the software will cause this functionality to be switched off. 21CFR11 functionality can then be re-enabled once the downgrade is complete by re-enabling the Features File (navigate to the Options pages and select "Enable Auditing" and "Enable Electronic Signatures" from the 21CFR Part 11 tab and "Enable Access Control" from the Access Control tab).

We recommend the MAC software is uninstalled in this way before updating to later versions (or even downgrading to earlier versions).

Software Categorization

GAMP 5

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they used are fit for purpose and meet current regulatory requirements. As part of this, the GAMP

committee has defined a series of software categories which are designed to help users in assessing the risk and validation requirements associated with using a specific software package.

In its standard mode of operation, the Mastersizer 3000 software provides users with a series of standard interfaces and functions that enable the software to be configured to meet specific user business requirements. These interfaces include the ability to define Standard Operating Procedures (SOPs) for sample measurement, create report definitions using pre-defined functions and develop data export templates using pre-defined parameters. If users apply these functions, then the software can be considered to be a Category 4 product.

In addition to the standard functions, the Mastersizer 3000 software provides users with the ability to modify the results reported by the system to fit their application requirements. This is achieved using the custom calculation reporting functions. These functions are not widely applied within regulated environments. However, if they are used to meet business requirements then the macros included within the custom calculations should be validated according to GAMP Category 5 requirements. Users are therefore encouraged to specifically validate any custom calculations applied within their reports and ensure these are documented. Where possible, we would encourage the use of the standard result reporting features, as this minimizes the risk of errors in the reported size distribution statistics.

USP<1058>

USP<1058> provides pharmaceutical users with guidance as to how the qualification of analytical systems should be carried out. As part of this guidance, the USP define a series of instrument categories. These instrument categories different from those described in GAMP 5, although the principles applied as part of the classification of a system are similar.

The Mastersizer 3000 is a computerized analytical system where the software provides users with the functions required to meet specific analytical application requirements. As such, it is a Group C instrument. Users are therefore recommended to define their requirements for the operation of the system and then compare these requirements to the claimed capabilities of the software and hardware. This should include an assessment of whether the new features and bug fixes included in a specific version of the Mastersizer 3000 software are necessary to meet business requirements.

Validation Support Documents

The Mastersizer 3000 software CD contains the following documents, which are provided to help users who work within validated laboratories:

- 21CFR Part 11 and Security System guides:
  Provide guidance on how to set up the features of the software in order to aid technical compliance to 21CFR Part 11.
- 21CFR Part 11 and Annex 11 Gap analysis documents:
  These detail the capabilities of the software and how these align with the requirements of 21CFR Part 11 and the equivalent rule set in Europe (Annex 11).
- Malvern Instrument's ISO Certificates:
  Copies of the current ISO9001:2008, ISO14001 and OHSAS 18001:2007 certificates, issued as part of the independent audit of Malvern's business management systems. This includes certification of the development of the Mastersizer 3000 software to TickIT Plus requirements.

- Software Certificates of Conformance:
  Copies of the software certificates of conformance for all Mastersizer 3000 software versions, providing a summary of Malvern's business management systems which are used for the development of the Mastersizer 3000 software and hardware.
- Software Update Notifications:
  Copies of the software update notifications for all Mastersizer 3000 software versions, confirming the new features and bug fixes introduced for each version.
- Software Update Verification Procedure:
  A procedure users can follow for verifying the success of a software upgrade.

Note:
The documents provided on the software CD are those which were current at the date the software was released. Please contact your local Malvern Panalytical representative if you need to verify if any updated documents are available.

Software License Files

The Mastersizer 3000 software requires a valid license file to run. When connected to an instrument, the system automatically generates this file and the user will be asked to accept the license.

Note:
If you wish to install the Mastersizer 3000 software on additional computers, you will need to follow the procedure below for sharing a software license.

Sharing a License for Mastersizer 3000 users

In order to enable the use of the Mastersizer 3000 on a computer which is not connected to a system, it is necessary for users to create a license. This can then be shared with other users, allowing them to gain access to the software.

To share a license, follow the steps below:

1. At the computer that is connected to the instrument, run the Mastersizer 3000 software and click on the Application Menu icon  at the top left of the screen.
2. Select About and click on the View License... button.
3. Click on the Share this License... button. The system tells you what information the license file contains.
4. To accept that information click Yes and choose a location to copy the file to (e.g. a memory stick).
5. At the separate computer, install the Mastersizer 3000 software from the CD and start the program. At the license screen, click the Install button.
6. Browse to the folder that contains the license file from step 4 above, and select the licensee file. The licensee details will be shown and you can now accept or decline the license.

Note:
The software license is specific to a given Mastersizer 3000 system. When a license is shared, detailed user and computer information is stored in the license file, ensuring it can be traced back to its source Mastersizer 3000 system. Users should only share the license with users within their organizations who need to analyze data off-line.

Note:
The software license must not be shared with other organizations without the consent of Malvern Panalytical.

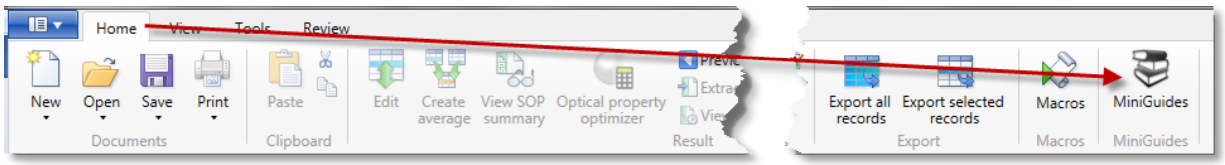
Sharing a License for Mastersizer 3000E users

The Mastersizer 3000E system is provided with a simplified, basic version of the Mastersizer 3000 software. This basic software version is restricted to use on a single computer workstation attached to the Mastersizer 3000E system. As such, the license sharing facility offered for Mastersizer 3000 users is not available.

Users of the Mastersizer 3000E system who want to be able to use the software on multiple workstations will need to purchase a software upgrade. This upgrade will enable the premium features associated with the Mastersizer 3000 software, including the ability to create shared licenses. Please contact your local Malvern representative if you would like to purchase this upgrade.

Software Guides

The Mastersizer 3000 software includes a comprehensive help system, which provides a functional description of each of the software elements. In addition to this, the software includes a series of 'MiniGuides', which provide an introduction to useful software tools and new features. These are accessed via the MiniGuides option on the Home ribbon bar:



Fixed issues list

The main issues fixed in v3.81 maintenance release of the Mastersizer 3000 software are confirmed in the table below:

Reference(s)	Issue
110089	Locking signatures does not work
110090	Opening the record signature history for a signed record causes software to crash
110344	Signatures are lost between versions of the software
110961	Opening the record signature history after overwriting signatures between versions causes software to crash
111510	Translation error in Japanese in SOP menu

Note:
This release also contains important security updates. In accordance with industry best practice, details are not published on these fixes.

Bug reference 110344: Signatures are lost between versions of the software

After the release of v3.80, we became aware of an issue related to the transfer of electronic locking signatures on upgrading to Mastersizer 3000 software versions 3.70, 3.71, 3.72 (3.7x) and 3.80.

- Any locking signatures applied to records in v3.63 or earlier will not be transferred across when the software is upgraded to versions 3.7x and 3.80.
- However, these locking signatures **can** be recovered through this v3.81 software upgrade (because the signature information associated with each locked record still exists within the record structure), provided you do not re-sign these records in v3.7x and v3.80.

The issue has arisen due to the introduction of a new software component used to read audit trail information in versions 3.7x and v3.80. This means that audit trail information written in the earlier format is not recognized by the new software component, causing the signing and locking status to be incorrectly reported.

This software release, v3.81, will reinstate visibility of the locking signatures that were applied in earlier versions of the software.

If you are on v3.63 or earlier:

- please upgrade to v3.81 (**do not** upgrade to v3.7x or v3.80).
- you will not see any loss of signatures

If you have upgraded to v3.7x or v3.80 and have not attempted to re-sign records that were previously locked:

- we **strongly recommend** upgrading to v3.81
- the locking signatures that were applied in version v3.63 or earlier and subsequently lost on upgrade to v3.7x or v3.80 will have their visibility reinstated

If you have upgraded to v3.7x or v3.80 and have re-signed records that were previously locked in v3.63 or earlier:

- we **strongly recommend** upgrading to v3.81
- re-signing will cause the original (v3.63 or earlier) locking signature to be superseded by the later (v3.7x or v3.80) locking signature
- in v3.81, the original (v3.63 or earlier) signed record will be visible in the signature history as an unsupported signature type, with no signatory detail. The later (v3.7x or v3.80) signature will be visible with the correct signatory state and full signatory detail

New Features and Fixed Issues in v3.80

The new features and fixed issues introduced in the previous software version 3.80 are given below:

New Features List: v3.80

The features implemented in v3.80 release(s) are confirmed in the table below:

Reference(s)	Feature
100465	Pre-clean step added for use with the Hydro MV and Hydro LV
91585	Advanced custom cleaning settings added to the 'Custom Clean' settings menu
101963	Cleaning progress bar displayed during the clean process

98243	Measurement records used to create an average record now visible as a column value for the average record
90760	Signature state of a non-final signed record now displays 'signed' instead of 'un-locked' in reports

Details of the new features developed for previous software releases can be found in the Software Update Notification documents stored on the software CD-ROM.

Fixed Issues List: v3.80

The main issues fixed in v3.80 maintenance release of the Mastersizer 3000 software are confirmed in the table below:

Reference(s)	Issue
86716	Software can crash when batch printing
89698	Software crashes when the network connection is lost during the saving of a measurement file to the network location
90914	Intermittent crash on Reports page when 'copy as raw data' crash
91050	Wrong warning message when editing a mix of Mastersizer 3000 and 3000E records
92424	User able to sign off read-only record, but changes are unsaved
92521	Using 'From Existing SOP...' functionality allows SOP permissions to be by-passed
92525	SOP prevented from saving or closing when errors exist on inactive functions
92951	Sample identifier text cut-off if on multiple lines
95123	Sample name not applied to SOP Player records from Sample Documentation window
95454	Software intermittently crashes on rare occasions software fails to access the dry accessory status
95532	Validation errors for Ultrasonics page in SOP
95682	Opening multiple records from network locations crashes the software
95717	Invalid report path crashes software at startup
96030	Audit Trail CSV export doesn't use French-compatible CSV format in French language Mastersizer 3000 software
96579	MS3000 installer is not localized in all support languages
96580	Signature action types are not localized in audit history
96620	'Replace this license' button cut off in Russian
96625	'Replace this license' button text not localised
98511	Report deleted upon edit if no write permissions on folder
100389	Batch Printing can take a long time, resulting in 'printer time-out' error
103433	New Report page is blank when cycling through report tabs
103439	Renaming New Report not functioning correctly

104137	Chinese and Japanese characters do not display correctly in audit export PDF
104324	Audit export translation doesn't work
104341	Audit export font doesn't support all Chinese and Japanese characters
106412	Binary audit trail 0 trim deserialization issue
107585	Audit trail export CSV broken for Chinese and Japanese characters
109295	Creation of a new report in Result Overlay results in inability to view data in original report
91263	Aero level sensor test not required on maintenance page

File Types and Locations

The Mastersizer 3000 software uses a series of different file types in order to store data and measurement settings. These are described below, in order to help users who wish to secure the Mastersizer 3000/3000E system using the Microsoft Windows security and access settings. Guidance regarding how to set up the security settings is provided in the Windows Security Settings section of this document.

File Type	Extension	Default Path	Advised security setting for 21CFR Part 11 Mode
21CFR11 mode: Audit trails (Mastersizer 3000 only)	.mpaf	*C:\ProgramData\Malvern Instruments\Mastersizer 3000\Audit Trails*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
User sizes	.siz	*C:\ProgramData\Malvern Instruments\Mastersizer 3000\User Sizes*	No control required as these settings are stored in SOPs.
User defined materials	.mmat	*C:\ProgramData\Malvern Instruments\Mastersizer 3000\Materials*	No control required as these settings are stored in SOPs.
User defined dispersants	.mdis	*C:\ProgramData\Malvern Instruments\Mastersizer 3000\Dispersants*	No control required as these settings are stored in SOPs.
Data quality addins (Mastersizer 3000 only)	.mdaq	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Data Quality Addins* Private workspace: *C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins*	No control required as the data quality tool only provides advice.
Export data	.txt.csv.rtf	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Export Data* Private workspace: *C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Export Data*	If data export is a critical part of the SOP used for your samples then you should prevent deletion of the files in this directory. However, read, write and modify access must be maintained.

Measurement data	.mmes	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Measurement Data* Private workspace: *C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.mrep	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Reports* Private workspace: *C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Reports*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained. Note: it is important that users are prevented from deleting reports via the software interface as well. This can be done using the MAC application.
SOP templates	.msot	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\SOP Template* Private workspace: *C:\Users\{user_name}\Documents\MalvernInstruments\Mastersizer 3000\Workspace\SOP Template*	No control required.
SOP	.msop	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\SOP* Private workspace: *C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Data export templates	.mext	Shared workspace: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Data Template* Private workspace: *C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Template*	No control required.
Licence file	.licence	Mastersizer3000.licence file stored in: *C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files*	Once the system has been set up and 21 CFR Part 11 mode engaged then access to this file must be set to prevent deletion. However, read, write and modify access must be maintained.
Security configuration file	.xml	Exported from the Malvern Access Configurator (MAC) application. The directory is user-specified. Malvern advise that the file should be stored in:	Prevent deletion this file once it is created. However, read,

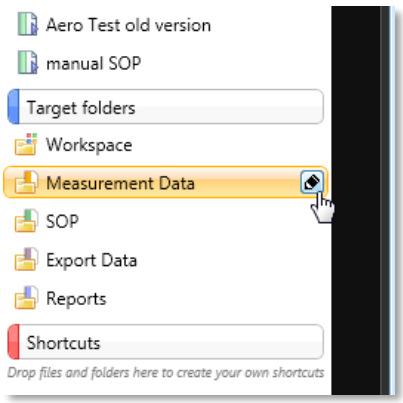
		C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files	write and modify access must be maintained.
Various system wide configuration files	Various	*C:\ProgramData\Malvern Instruments\Mastersizer 3000*	Full access must be maintained to this directory for the program to function correctly.

Changing the destination path for a file

The following folders can be configured from within the Mastersizer 3000/3000E software:

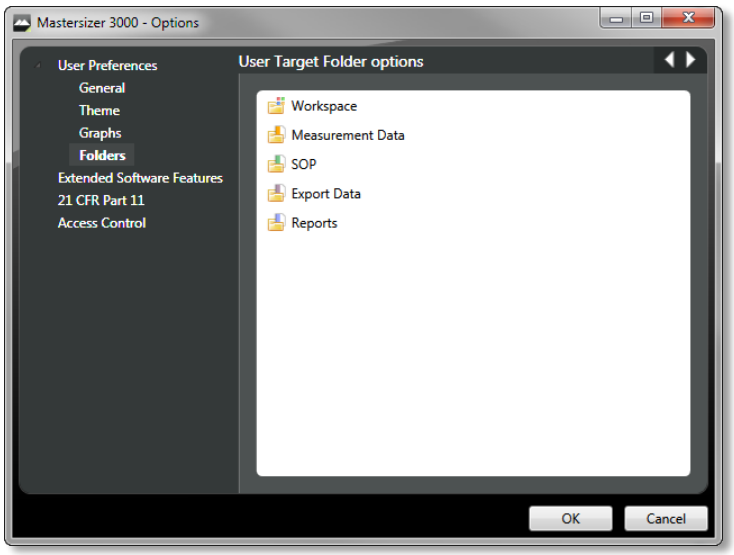
- SOP
- Measurement
- Data Reports
- Export Data

For Mastersizer 3000 users and those who have upgraded the Mastersizer 3000E software, the default file location for these files can be configured via the Target Folders section of the Workspace viewer. To do this, click on the pencil icon which appears when you hover over the directory shortcut:



Changing the directory associated with this shortcut will change the default directory accessed by the Mastersizer 3000 software for the selected file type.

Configuration of the target directories can also be configured from the User Preferences-Folders section of the Options menu:



Again, hover over the shortcut and click on the pencil icon in order to change the target directory. Note that this is the only place in the software where the target directories can be configured when using the Basic software for the Mastersizer 3000E.

Making a backup of the files

The Mastersizer 3000 software does not create backup copies of any of the file listed above. However, there are third-party software tools that will allow you to schedule regular backups, if required, for each of the file locations.

Windows Security Settings

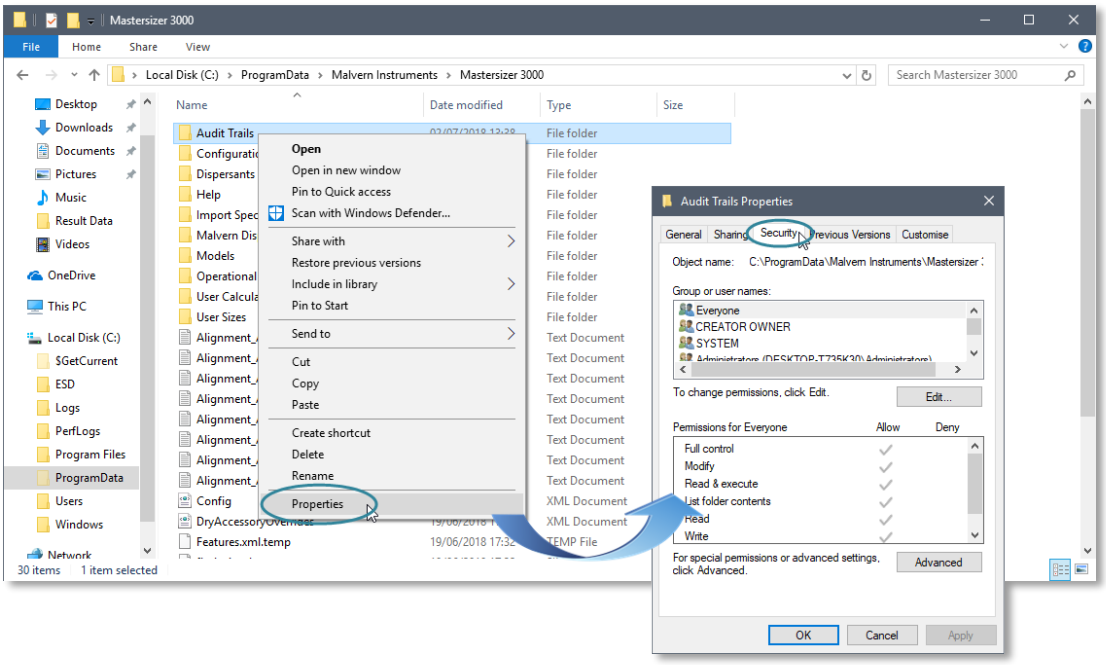
With a 21CFR11 compliant computer system, one of first concerns to address is the potential for the loss of data; either accidently, or by intention. Utilizing the built-in security tools of Microsoft Windows®, an IT professional can effortlessly change user access to specific files and/or folders by simply removing certain file/folder permissions.

For the next part of this document, it is assumed that you have the required administrator rights for the system upon which the Malvern software is being installed; allowing you to install, or update software and configure windows security permissions.

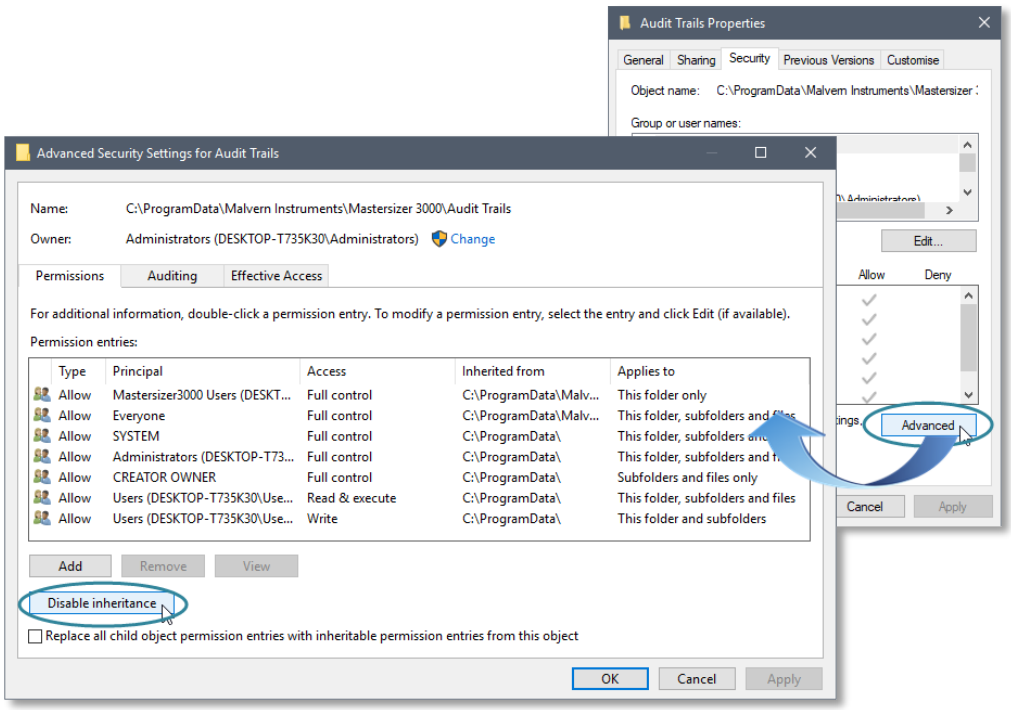
Note:
For the following demonstration we have previously created a user group, through the Computer Management console, called 'Mastersizer3000 Users'. This user group will later be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to any other output folder requiring limited user access. In the following illustrations, we have not removed default groups such as 'Everyone' or 'Users' - these can be deleted or used as an alternative to dedicated user group/s. However, when using these groups, we strongly advise that explicit 'Denies' are not used, unless you fully understand the Microsoft® file/folder security permissions.

Changing the folder security permissions in Windows 10

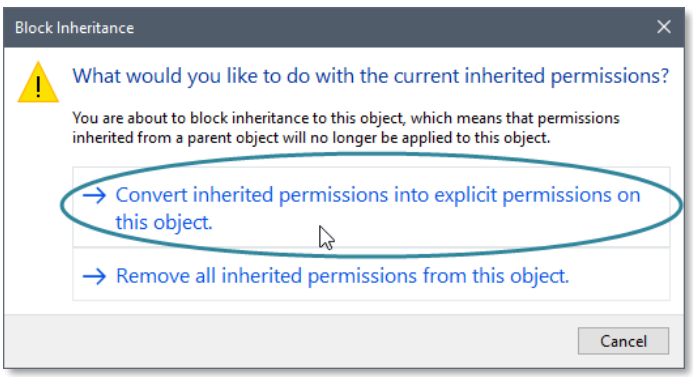
1. Navigate to one of the folders that needs to be secured - in this case we have selected the folder where the Mastersizer audit trail files are stored. Right-click on the folder and through the context menu open the folder Properties.



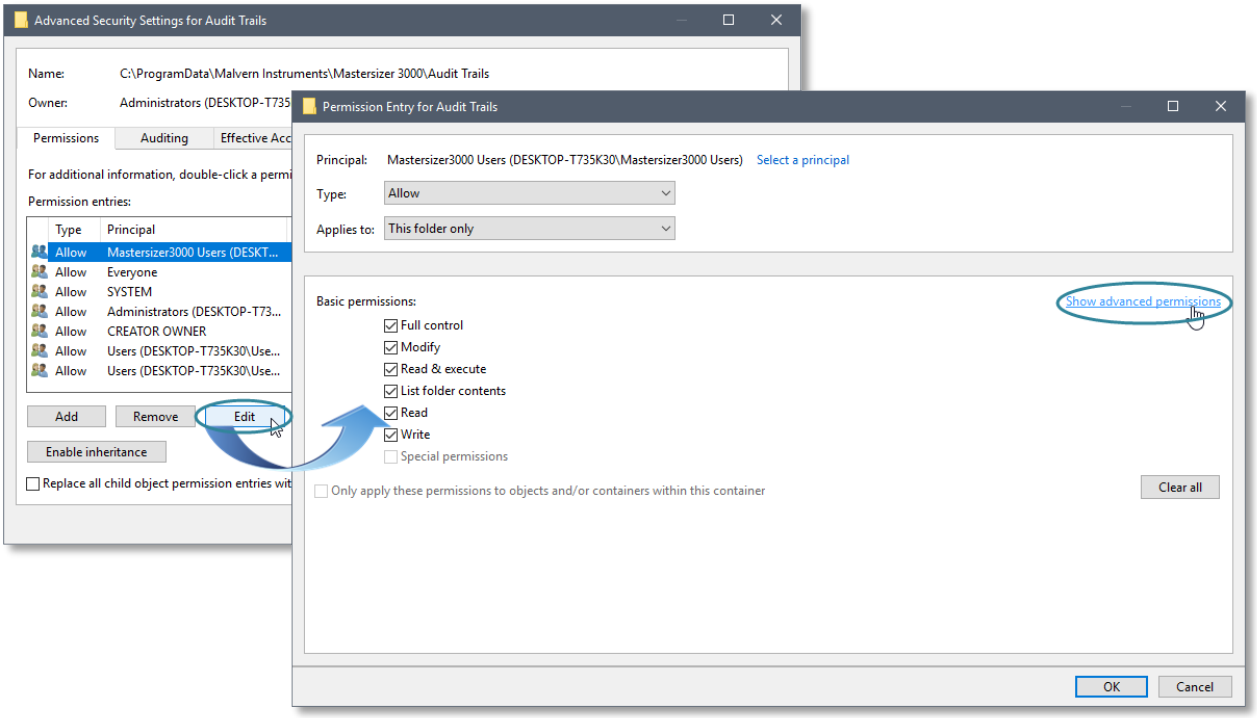
2. Within the **Audit Trails Properties** dialogue, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings**.
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button:



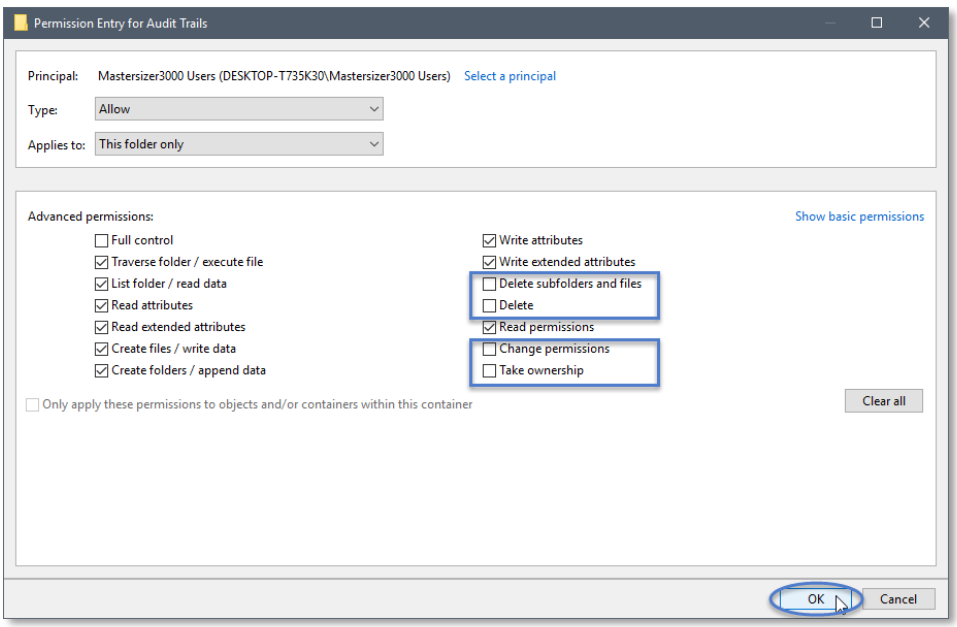
4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the any current users and groups settings.



5. After returning to the **Advanced Security Settings** window, left-click to select the **Mastersizer3000 Users** group and then left-click the **Edit** button.
6. In the **Permissions Entry** window, left-click the **Show advanced permissions** to reveal the full permissions list.

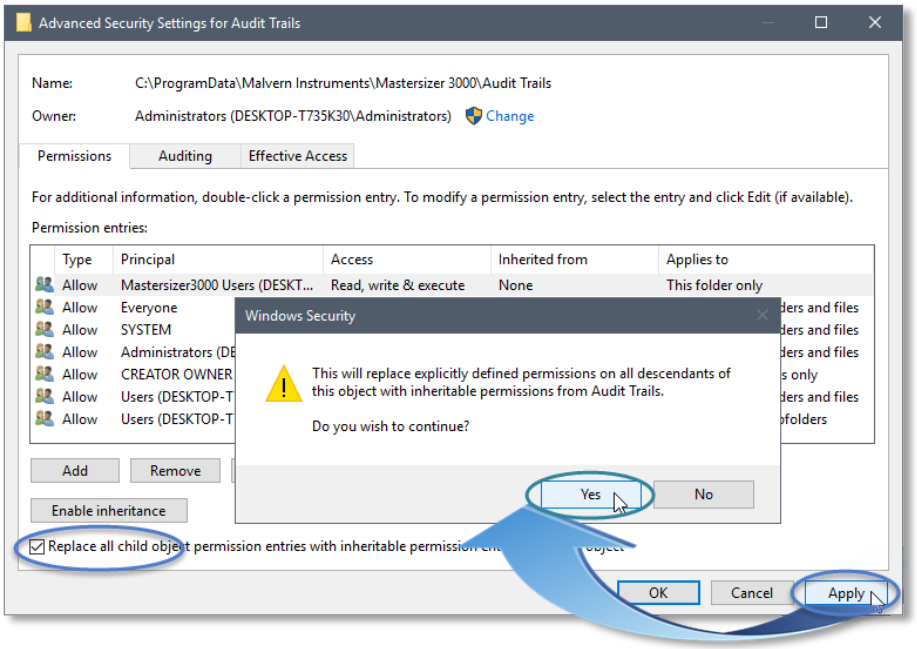


7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.

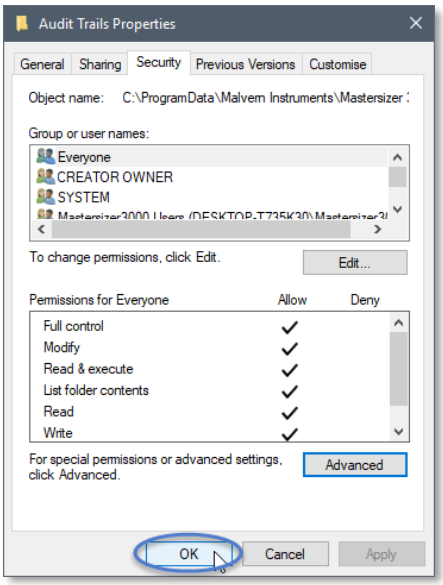


8. Left-click **Replace all child permission entries with inheritable permission entries from the object** and left-click the **Apply** button.

9. Left-click the **Yes** button when prompted to replace the permissions and the **OK** button when you return to the previous window.

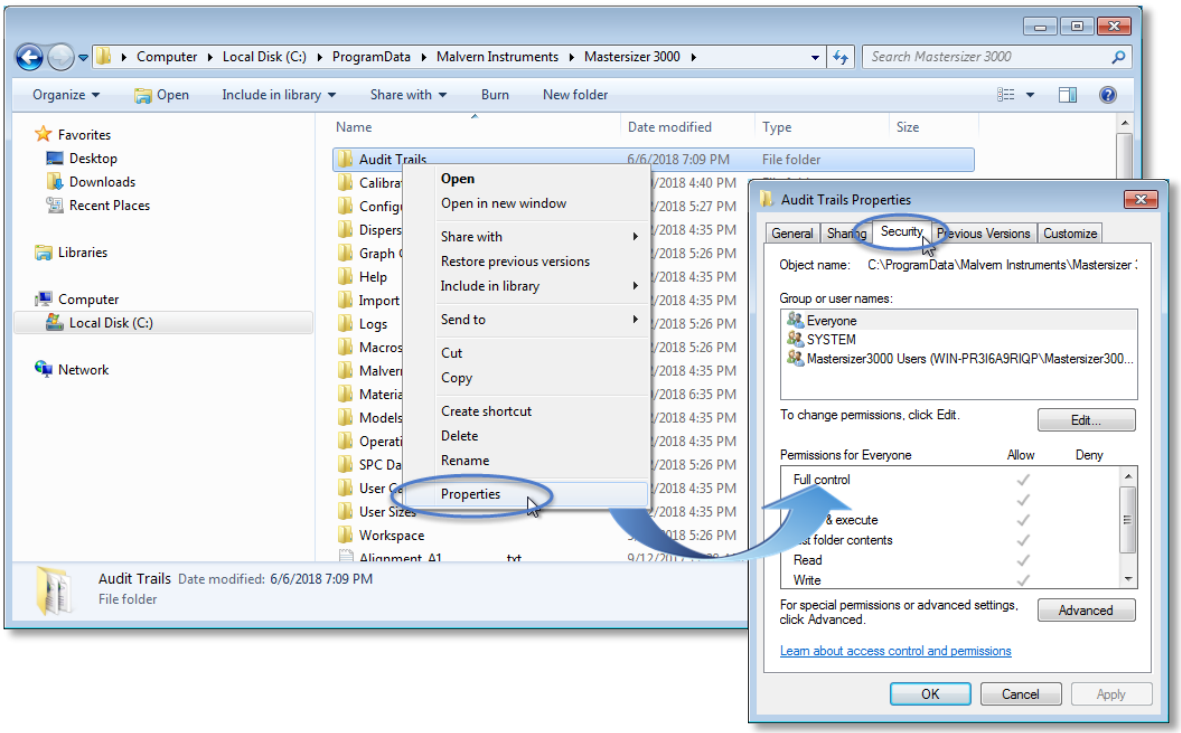


10. Left-click the **OK** button when you return to original folder properties window.



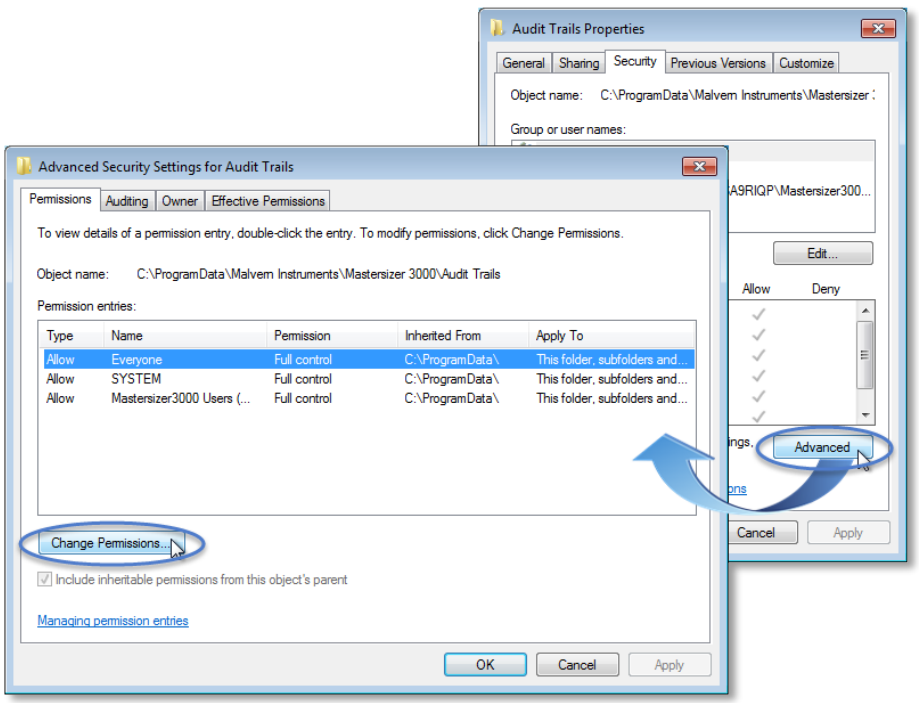
Changing the folder security permissions in Windows 7

1. Navigate to one of the folders that needs to be secured - in this case we have selected the folder where the Mastersizer audit trail files are stored. Right-click on the folder and through the context menu open the folder **Properties**.

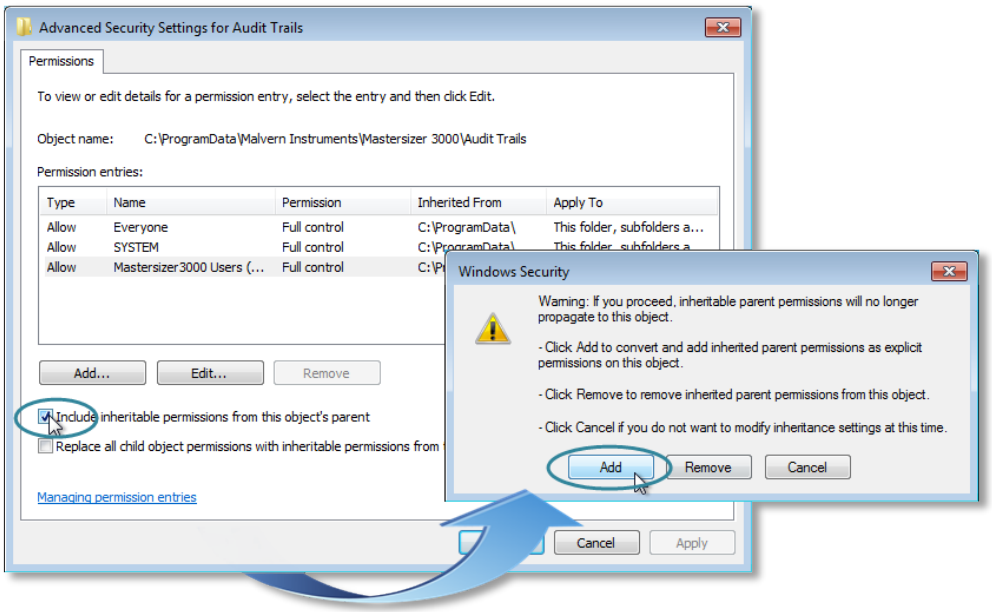


2. Within **Audit Trails Properties**, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings.**

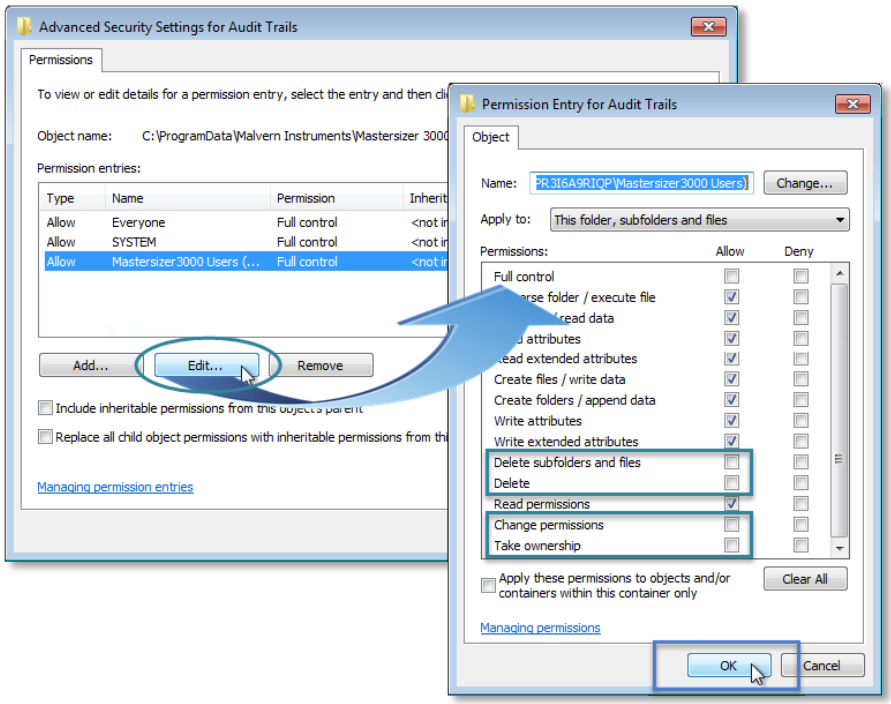
3. Within the **Advanced Security Settings** left-click the **Change Permissions** button. This will open an identical with the options to change the inheritable permissions.



4. In the second the **Advanced Security Settings** window, left-click to deselect the **Include inheritable permissions from this object's parent** check-box and when prompted left-click the **Add** button to convert and add the inherited permissions from parent.

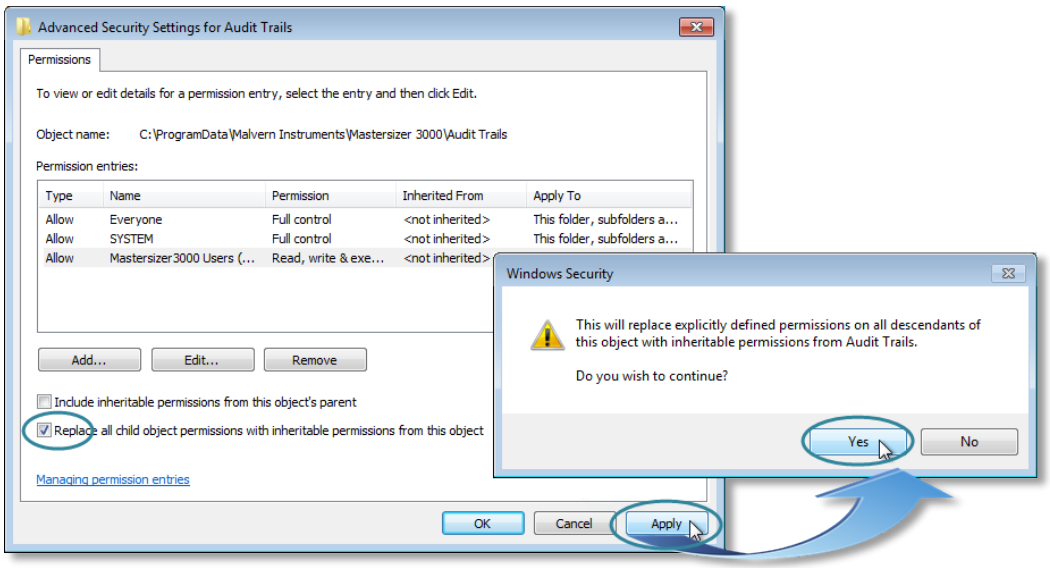


5. Left-click to select the **Mastersizer3000 Users** group and left-click the Edit button to open the **Permissions Entry** window.



6. Left-click to deselect the **Delete subfolders and files**, **Delete**, **Change permissions** and **Take ownership** check-boxes and finish by left-clicking the **OK** button. Warning, do not select the check-box **Apply these permissions to objects and/or containers within this container only.**

7. Returning to the previous window, left-click the **Replace all child object permissions with inheritable permissions from this object** check-box and when prompted to confirm left-click the **OK** button.



8. Left-click **OK** on the remaining windows to close them.

Known Issues

The following software bugs have been discovered within the software, and will be investigated as part of a future release. Please follow the suggested work-around for each issue when operating the software.

Issue	Work Around	Comment
Accessory status bar is green but SOP and Manual measurement options greyed out.	From time to time the SOP and manual measurement options are still greyed out even when the accessory status bar is green. To re-enable these options, right-click on the accessory status bar and reselect the accessory.	Intermittent Observation
Reporting of zero measurements.	In rare cases a zero measurement can occur in both wet and dry measurements. The measurement record contains background and data but no signal information. A zero distribution is recorded in the measurement file. No work-around available.	Medium risk issue
Software can crash when batch printing	When selecting too many reports and/or too many records for batch printing, an error can occur causing a crash exception.	Low risk issue

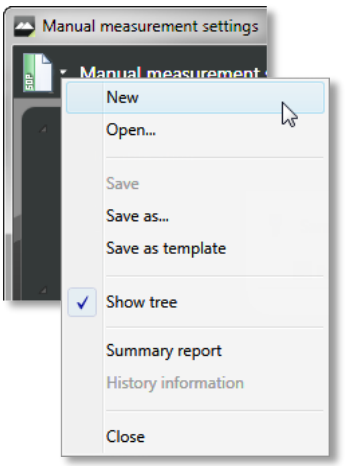
	Restricting the total number of pages printed to 220 or less (equivalent to 13 results batch printed with 10 reports) will mitigate this issue occurring	
Aero S and Aero M sample feed control	When carrying out manual measurements it is possible to enable the sample feed for the Aero dispersion unit with the vacuum and dispersion air switched off by clicking the Feed button twice within the accessory controls. After approximately ten seconds the system will switch back into standby mode and an 'insufficient exhaust vacuum / air achieved' error message will be displayed. However, some sample may be lost.	Error can be avoided procedurally (avoid double-clicking the feed button).
Corrupt report settings file causes software crash on start-up	It has been observed that the global report settings file may become corrupt. This file holds the company name and logo used across all reports in the software. A symptom of this issue is the software crashing on start-up with an exception "hexadecimal value 0x00, is an invalid character". The workaround is to delete the contents of folder at *C:\ProgramData\Malvern Instruments \Malvern.Reporting*. This will trigger a new fresh settings file to be created – you will have to reconfigure your company name and logo in reports.	Medium risk issue
Warnings are displayed about corrupt measurement files	The software has built in detection of when measurement files are at risk of being corrupted. If you see one of these messages, you are probably creating too large a measurement file.	Intermittent Observation
Instrument disconnects after firmware upgrade	An issue has been seen for some installations whereby the instrument will become disconnected from the computer following a firmware upgrade. Turning the instrument off and on again will cause it to successfully reconnect to the software.	Intermittent Observation
The manual measurement settings do not match the connected/active dispersion unit.	See known issue description below.	Intermittent Observation
Some text still appears in English when running with a different language selected.	The translation of all software text will continue in future releases.	Low risk issue
Software does not open all files selected when they are opened using Windows Explorer.	Use the Open menu option in the Mastersizer 3000 software to open multiple files.	Low risk issue
The system audit trail displays duplicated columns for each language under which the system	No work-around available.	Low risk issue

has been run when auditing has been enabled.		
Various fields in the Edit result window lose their 'edited' blue background appearance when a different page in the editor is selected.	No work-around available. This is a display issue only, as the software correctly applies the edit values when the OK button is pressed.	Low risk issue
Trend table print out is limited by paper size	Report widgets are designed to fit on one page, and will not wrap over pages. If you select lots of measurement records, the trend table widget will expand to fill the page. However, if you select more measurement records than can fit in a trend table on a single page then the displayed records will be truncated at the page boundary. The only work around for this issue is to print the report on a larger paper size. Paper size A4 has a limit of 56 records in a trend table, whereas paper size A3 has a limit of 86 records.	Low risk issue
Some parameters are not imported from Mastersizer 2000 measurement records	When importing Mastersizer 2000 measurement records into the Mastersizer 3000 software, some SOP parameters from the Mastersizer 2000 records do not get imported. However, all of the parameters required for result review or recalculation are present.	Low risk issue
Manual measurement errors are reported if the Aero dispersion unit configuration has changed between measurements	The manual measurement feature in the software stores the last used settings. This includes configuration of the Aero dry powder disperser. If you change the configuration between measurements and then open a manual measurement, the software will report an error stating that configuration is wrong. If this happens, close and re-open the manual measurement window and change the manual measurement settings to match your new Aero configuration.	Low risk issue
Software exception is reported if the software is closed when a macro is running	All currently running macros must be closed before closing the software.	Low risk issue
Some report widgets are truncated in the print preview view	Some report widgets may not be displayed correctly within the print preview screen. However, if the report is printed all of the information within the widget will be shown.	Low risk issue
Software may crash when exporting data with custom sample identifiers which start with a number	Exporting measurement data with custom sample identifiers beginning with a number will cause the software to crash when you select an export template that contains sample identifiers. The	Low risk issue

	only work- around is to prefix sample identifiers with letters.	
Ultrasound SOP option 'Continuous (From Measurement Start)' does not turn off in SOP playlist	If you use an SOP with the ultrasound option 'Continuous (From Measurement Start)' in an SOP playlist, when running a subsequent SOP with no ultrasound turned on, the ultrasound will not turn off as expected. The work around is to use the 'Continuous (From Sample Addition)' option in the SOP rather than 'Continuous (From Measurement Start)'. When this playlist is run, then the ultrasound will turn off when executing a subsequent SOP which does not require ultrasound.	Low risk issue
Cannot load old custom calculations from file	When trying to load a custom calculation created in v3.30 software or earlier, the software may report error and the calculation will not load. The workaround is to re-export the custom calculation from the original report in a recent version of the software.	Low risk issue
Data quality tab is not displayed immediately when selected from the extended features list	Given that the software has just been installed and the option to enable the extended software features is selected. Then when the application is restarted the data quality tab will not be displayed if the default view is selected. The work-around is to select the 2-pane vertical view which will display the data quality tab. Then reverting to the default view will display the data quality tab.	Low risk issue
Ultrasound level applied during clean reported as 0%	You may find that the measurement manager reports that 0% ultrasound is being applied during cleaning when you have set an ultrasound demand of greater than 0%. Evidence suggests that ultrasound is applied correctly as per the configured ultrasound demand, but the value shown in the measurement window is incorrect.	Low risk issue
"Some data may be missing" error message on attempting to resign records created in v3.30 or earlier	This is a false-positive error message, a consequence of a design issue fix implemented in v3.40 onwards. In earlier versions of the software (v3.30 and earlier), duplicate parameters were written to the measurement record. From v3.40 onwards, a fix was applied which enabled the duplicate parameters to be disregarded. However, this means that when a measurement is created in v3.30 or earlier, and then signed in a later version of the software, the signature information is written over the top of the duplicate data, causing the false-positive error message to be generated.	Low risk issue. The error message is a false-positive (data is not missing) and locking signatures are not lost on v3.81, so it is unlikely a user will need to resign a record.

Downgrading v3.81 with 21CFR11 mode enabled to earlier versions of the software will cause this functionality to be switched off	Re-enable 21CFR11 functionality once downgrade is complete	Medium risk

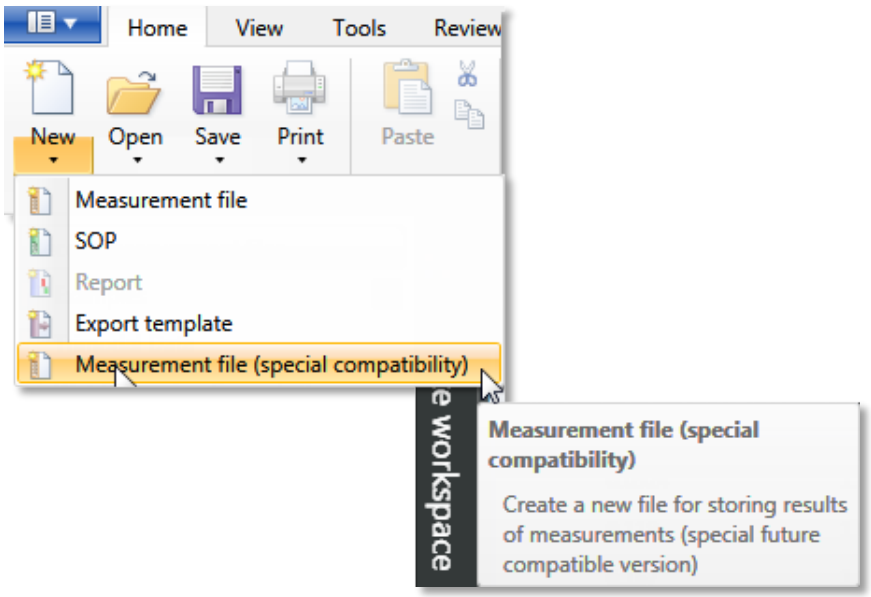
Manual measurement settings do not match the connected / active dispersion unit



Occasionally, users may see the wet accessory related manual measurement settings when a dry unit is attached, or visa-versa. If this occurs, open the manual measurement settings window and click the New menu item from the Window Features menu:

This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software, but does not occur on all systems.

Measurement File Format



In v3.40 of the Mastersizer 3000 software we have re-introduced the file format used in older versions of the software (v3.10 and earlier) due to an incompatibility issue we discovered when the software's 21 CFR Part 11 features are enabled. This format is now selected by default and offers the advantage that it is compatible with all earlier versions of the software.

Note that files created using v3.20 and v3.30 of the Mastersizer 3000 software can still be opened, edited and saved using v3.40. The software will automatically switch to the correct file format if you select a file created in these versions. If you want to specifically create a file in the same format used by v3.20 and v3.30, select the Measurement file (special compatibility) option when creating a new measurement file:

Measurement File Size and Corruption Warnings

Version 3.20 and higher of the Mastersizer software includes the ability to detect when measurement files are at risk of becoming corrupted. If you see one of these messages, you are probably creating too large a measurement file. We

recommend that you keep measurement files to a maximum size of 100 records, and advise that you try to remember to regularly create and use new files to store measurement records.

Note that Malvern are currently investigating possible alternative measurement file formats for use in future software releases, with the goal of increasing the maximum number of records which can be robustly stored within a single file.

Backward Compatibility

This software is only compatible with the Mastersizer 3000 (MAZ3000) and Mastersizer 3000E (MAZ3010) systems, and cannot be used with the Mastersizer 2000 (APA2000) or Mastersizer 2000E systems. It is possible, however, to review Mastersizer 2000 / 2000E results within the Mastersizer 3000 / 3000E software. Please refer to the user manuals and software help for guidance as to how this is achieved.

Analysis Error codes

The following error codes may be returned by the analysis routine as a result of data collection or result calculation errors:

Error Code	Description
1 4 5 44	Error detected with the selected material or dispersant optical properties.
3 6 7	Unable to load or generate a scattering matrix.
8	Unable to initialize the result calculation routine.
9	There is no raw data to analyze.
10	Unable to apply the selected analysis settings.
11 12	Error occurred during generation of the scattering matrix.
13	Error occurred during raw data handling.
14 15	Unable to configure the result calculation routine.
16 17	Unable to generate a result based on the input raw data.
18 20 22	Could not find any particle size distribution modes in the result.
19	The analysis residual is greater than 99.9%.

23 24	Error occurred when using the Fraunhofer analysis model.
25	Corrupt analysis settings detected.
40 41 42	Scattering matrix calculation settings errors detected.
43	Error occurred while generating the scattering matrix.
45	Matrix generation is currently busy.

MALVERN PANALYTICAL

Malvern Panalytical Ltd.
Grovewood Road, Malvern,
Worcestershire, WR14 1XZ,
United Kingdom

Tel: +44 1684 892456
Fax: +44 1684 892789

Malvern Panalytical B.V.
Lelyweg 1, 7602 EA Almelo,
Netherlands

Tel: +31 546 534 444
Fax: +31 546 534 598

info@malvernpanalytical.com
www.malvernpanalytical.com